

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MASAJI ISHIGURO, TAKASHI NAKATSUKA,
RIE TANAKA, TETSUO SHIMAMOTO, and TAKURO YOSHIDA

Appeal No. 2001-1045
Application No. 09/178,594

ON BRIEF

MAILED

AUG 30 2002

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before WINTERS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 15-19, all of the claims remaining. The claims are directed to a method of making a 4-substituted azetidinone derivative by reacting an azetidinone derivative with an ester in the presence of a catalyst. The claims are reproduced in an appendix attached to the Appeal Brief.

The examiner does not rely on any references.

Claims 15-19 stand rejected under 35 U.S.C. § 112, first and second paragraphs. We affirm.

Discussion

The claims are directed to method for making 4-substituted azetidinone derivatives, which are useful as synthetic intermediates of "carbapenem based antimicrobial agents." See the specification, page 1.

All of the claims subject to each rejection stand or fall together. Appeal Brief, page 3. Claim 15 is the broadest claim subject to each rejection and therefore we decide the issues on appeal based on representative claim 15. Claim 15 is directed to a method of making a 4-substituted azetidinone derivative by reacting an azetidinone derivative in the presence of either a copper compound or zinc and a copper compound, with an ester having substituents designated "X", "Y", and "R₃". The "X" and "Y" moieties are defined as members of a large Markush group, alternatively substituted with substituents selected from another large Markush group. R₃ is defined as "a protective group [that is] easily removed."

The examiner rejected claims 15-19 "under 35 U.S.C. § 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention." Examiner's Answer, page 3. The examiner states that "[f]ive issues arise," all but one of which apply to all the claims. Id.

Each of the "issues" discussed by the examiner appears to be a separate ground of rejection under either the first or second paragraph of 35 U.S.C. § 112.

Each of the issues concerns the written descriptive support for or definiteness of a different claim limitation, each must be separately considered in light of the record, and each is potentially an independent basis for holding the claims unpatentable. Thus, it might have been clearer to present each "issue" as a separate ground of rejection, under the appropriate paragraph of § 112, applied to the appropriate claims. However, the examiner has made clear his bases for holding the claims unpatentable, and has made clear which basis applies to which claims. We therefore proceed to the issues set out in the Examiner's Answer.

1. Description of the catalyst

The examiner rejected claims 15-18 on the basis that the specification does not provide an adequate description of the "(b)" catalyst, viz. zinc combined with a specified copper compound. The examiner acknowledges that the use of zinc itself as a catalyst is described, as well as zinc combined with cuprous bromide ethyl sulfide complex, but found that the claim language went "beyond what the specification actually says." Examiner's Answer, page 3.

The examiner bears the initial burden of showing prima facie unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996). "Insofar as the written description requirement is concerned, that burden is discharged by 'presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.' . . . If . . . the specification contains a description of the claimed invention, albeit not in ipso verbis (in the identical words), then the

examiner . . . , in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient." Id.

In this case, the examiner appears not to have fully appreciated the specification's disclosure. The specification makes clear that two methods of making 4-substituted azetidinone derivatives are being disclosed, one comprising catalysis with a copper compound alone and one comprising catalysis with zinc plus a copper compound. See, e.g., page 4, line 8 to page 5, line 15:

The present inventors found that an ester compound represented by the general formula (2) . . . can be treated with a metal base to give the corresponding metal enolate, which can then be reacted with an azetidinone derivative represented by the general formula (1) . . . in the presence of a copper compound to produce a 4-substituted azetidinone derivative represented by the general formula [3]. . . .

At the same time, it was found that an ester compound represented by the general formula (2) . . . can be reacted with an azetidinone derivative represented by the general formula (1) . . . in the presence of zinc and copper compounds to produce a 4-substituted azetidinone derivative represented by the general formula [3].

(Bracketed material in original.) On page 8, the specification lists a number of copper compounds suitable for use as catalysts. This list follows immediately after another discussion of the alternative reaction, "when the ester compound . . . is reacted with the azetidinone derivative . . . directly without converting to the corresponding metal enolate . . . in the presence of zinc and copper compounds." See page 7, lines 34-39. Thus, it is clear from the discussion in the specification that the alternative, direct conversion process is intended to be practiced using as a catalyst the combination of zinc and one or more of the listed copper compounds, just as recited in the claims.

Since we find the zinc plus copper compound catalyst to be adequately described in the specification, we reverse the examiner's first ground of rejection.

2. Description of the X and Y moieties

The examiner rejected claims 15-19 because the specification does not adequately describe some of the groups included within the Markush group of possible X and Y moieties on the ester reactant. See the Examiner's Answer, pages 4-5. The examiner specifically noted that the claims included carboxyl groups and thiocarboxyl groups as possible X and Y moieties; the examiner found that these groups in particular lacked adequate descriptive support.

We agree with the examiner on this point. The specification includes an extensive list of possible X and Y moieties (page 1, line 36 to page 2, line 22) but this list does not include carboxyl groups or thiocarboxyl groups. The examiner has therefore carried his burden of showing prima facie lack of adequate written description. See In re Alton, 76 F.3d at 1175, 37 USPQ2d at 1583: "If the applicant claims embodiments of the invention that are completely outside the scope of the specification, then the examiner . . . need only establish this fact to make out a prima facie case."

Appellants argue that the specification, at pages 1 and 2, states that X and Y can be, inter alia, "substituted or unsubstituted ester groups [or] substituted or unsubstituted thioester groups." Appeal Brief, page 4. Appellants also argue that on "pages 15 et seq., numerous preferred examples of the groups represented by X and Y are set forth." Appeal Brief, page 4. Finally, Appellants

argue that the working examples show various reactive groups in the X and Y positions. Appeal Brief, page 5.

These arguments are not persuasive. We have reviewed the portions of the specification relied on by Appellants but we have not found a description of carboxyl or thiocarboxyl groups at the X or Y positions. Pages 1 and 2 of the specification are discussed above; they do not describe a carboxyl or thiocarboxyl group as a possible X or Y moiety. Page 15 (starting at line 16 and continuing to page 16, line 9) does indeed described "[p]referred examples of the groups represented by X and Y." Those groups, however, do not include carboxyl groups or thiocarboxyl groups. Page 16, lines 10-15, states that "[t]hese alkyl, alkenyl, aralkyl, [etc.] groups may be substituted in their individual groups with one or more substituents, for example, . . . carboxyl group," but a carboxyl-substituted alkyl group (for example) is not the same as a carboxyl group per se. Nor do any of the working examples pointed to by Appellants show X and Y substituents that are either carboxyl (i.e., COOH) or thiocarboxyl (i.e., COSH) groups.

Thus, Appellants have not shown that the specification describes the claimed invention as including carboxyl or thiocarboxyl groups as possible X and Y moieties, either in ipsis verbis or in terms that would be understood by those skilled in the art as showing possession of such an invention. Appellants have therefore not rebutted the examiner's prima facie case of inadequate written description. We therefore affirm the rejection of all the claims on this ground.

3. Description of substituents on X and Y

Also on the subject of written description, the examiner rejected claims 15-19 because the specification does not adequately described the recited substituents on the optionally substituted X and Y moieties. See the Examiner's Answer, pages 5-6. The examiner specifically pointed to the recitation in claim 15 that the X and Y groups can be substituted with a carboxyl, thiocarboxyl, ester, or thioester group.

Appellants argue that "[o]n page 17 of applicants' specification at lines 3 et seq., a wide variety of substituents are cited which can be present. While it may not be possible that each and every combination of X and/or Y with the substituent disclosed may exist chemically, it is respectfully submitted that this should not be a bar to applicants defining X, Y and possible substituents in their claims." Appeal Brief, pages 4-5.

Again, we agree with the examiner. The specification lists possible substituents for the X and Y moieties (pages 17-18). The specification states that possible substituents for alkyl (including alkylthio and alkyloxy) groups include carboxyl, ester, and thioester groups. Page 17, lines 6-15. The same applies to possible substituents for alkenyl, alkenylthio, alkenyloxy, aralkyl, aralkylthio, aralkyloxy, aryl, arylthio, aryloxy, amino, carbamoyl, carbamoyloxy, imino-lower-alkyl, imino-lower-alkylamino, and amide moieties. See page 17, line 16, to page 18, line 17. However, none of the possible substituents includes the thiocarboxyl group recited in claim 15.

Thus, the examiner has shown that Appellants are “claim[ing] embodiments of the invention that are completely outside the scope of the specification.” In re Alton, 76 F.3d at 1175, 37 USPQ2d at 1583. He has therefore carried his burden of showing a prima facie lack of adequate written description. Appellants have pointed to nothing in the specification literally describing X and Y groups substituted with a thiocarbonyl substituent, nor have they shown that those of skill in the art would have understood the specification to show possession of such an embodiment. We therefore we affirm the rejection of all the claims on this ground.

4. Description and definiteness of R₃

Claim 15 defines the R₃ group of the ester reactant as “a protective group easily removed.” The examiner rejected the claims on the basis that the specification lacks an adequate description of R₃ as defined in the claims. He noted that the specification defines R₃ as follows:

The group represented by R₃ is not particularly limited, only if it can eliminate from the esterified carboxyl group represented by CO₂R₃ through hydrolysis or under conditions of the selective procedure according to the type of esters, and its preferred examples include those capable of forming the following esters: [a long list of esters], etc.

Specification, page 13, line 13, to page 14, line 34.

The examiner noted that, in contrast to the specification’s disclosure that the protective group must be removable by hydrolysis or some kind of “selective procedure,” the claim encompasses any protective group that is “easily

removable.” He therefore concluded that the definition of R₃ lacked adequate descriptive support in the specification.

The examiner also rejected the claims on the basis that the limitation “easily removed” is indefinite. He noted that the phrase “easily removed” does not occur in the specification, and the specification provides no other guidance to distinguish between protective groups that are “easily” removed and those that are “not easily” removed. He concluded that it is unclear which protective groups are, and which are not, encompassed by the claims. See the Examiner’s Answer, page 7.

Again, we agree with the examiner. Although the claim limitations need not appear in the same words in the specification, the description provided by the specification must show possession of the invention defined by the claims. In this case, nothing in the specification suggests that the description of protective groups removed by hydrolysis or some kind of “selective procedure” shows possession of the “easily removed” protective group recited in claim 15.

With respect to the definiteness of the “easily removed” limitation, we note that terms of degree, such as “easily,” are not per se indefinite. “When a word of degree is used the [examiner] must determine whether the patent’s specification provides some standard for measuring that degree.” Seattle Box Co. v. Indus. Crating & Packaging, Inc., 731 F.2d 818, 826, 221 USPQ 568, 574 (Fed. Cir. 1984). See also Ex parte Anderson, 21 USPQ2d 1241, 1249 (Bd. Pat. App. Int. 1991) (Where terms such as “superior” and “comparable” are not defined in the specification, “the issue is whether one skilled in the art at that time would have

been able to reasonably determine their metes and bounds in the context they are used.”).

Here, we agree with the examiner that the specification provides no standard for distinguishing protective groups that are “easily removed” from other protective groups. The only discussion of the R_3 protective group in the specification is the passage on page 13 quoted above. That discussion sheds no light on what makes a protective group “easily removed.” The specification does not indicate, for example, that the property of being eliminated via hydrolysis or a “selective procedure” is the defining characteristic of easily removed protective groups, or whether easily removed protective groups are a subgenus of those discussed on page 13-14. In short, the specification provides those skilled in the art with no hint as to how to distinguish the easily removed protective groups recited in the claims from other protective groups.

Appellants argue that “one of ordinary skill in the art to which this invention pertains, would be aware that a wide selection of R groups could be employed as long as they do not adversely affect the substitution reactions.” Appeal Brief, pages 3-4. Appellants also point to the above-quoted language from page 13 of the specification, and argue that this passage “indicate[s] that the R_3 group is not particularly limited. . . . Applicants submit that in the absence of prior art and in view of the large number of ester groups described, it would be unduly limiting to be required to restrict the R_3 group, particularly since it does not undergo any change in the substitution reaction.” Appeal Brief, page 4.

Appellants' arguments seem directed more to the issue of enablement than to written description or definiteness. The issue here is not whether those skilled in the art would be aware that the claimed method could be practiced using a broader range of R groups than is described by the specification. The issue with respect to written description is whether "the applicant had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him."

In re Blaser, 556 F.2d 534, 537, 194 USPQ 122, 124-25 (CCPA 1977).

Appellants' argument provides no basis on which to conclude that the specification meets this standard. Nor does it provides a basis on which to conclude that the metes and bounds of the claims would be apparent to those skilled in the art, as required by the second paragraph of 35 U.S.C. § 112.


With respect to Appellants' second argument, it is not "unduly limiting" to require an applicant to limit his claims to what is described as the invention in the specification, or to require him to use language that has a definite meaning. On the contrary, claims that are not so limited are unpatentable under 35 U.S.C. § 112 because they are inadequately described or indefinite.

Summary

We reverse the rejection based on the written description of the catalyst, but affirm the rest of the examiner's rejections.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED


Sherman D. Winters
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge


Lora M. Green
Administrative Patent Judge

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